K061410

510(k) Summary

SEP - 8 2006

ADMINISTRATIVE INFORMATION

Manufacturer Name:	Zimmer Dental, Inc. 1900 Aston Ave. Carlsbad, CA 92008 Telephone (760) 929-4300 FAX (760) 431-7811
Official Contact:	Kerry Foote
Representative/Consultant:	Floyd G. Larson PaxMed International, LLC 11234 El Camino Real, Suite 200 San Diego, CA 92130 Telephone (858) 792-1235 FAX (858) 792-1236

DEVICE NAME

Classification Names:	Implant, Endosseous, Root-Form
Trade/Proprietary Name:	Zimmer Dental Implants – Immediate Loading Indication
Common Name:	Dental Implant

ESTABLISHMENT REGISTRATION NUMBER

The Establishment Registration number for Zimmer Dental is 2023141. The owner/operator number is 1822565.

DEVICE CLASSIFICATION

FDA has classified "Implant, Endosseous, Root-Form" as a Class II device (21 CFR 872.3640). This device classification is reviewed by the Dental Devices Branch. The product code is DZE.

INDICATIONS FOR USE

The *Tapered Screw-Vent*®, *Screw-Vent*®, *AdVent*®, and *Zimmer*® One-Piece 3.7 mm Dental Implants are designed for use in the maxilla or mandible for immediate loading or for loading after a conventional healing period. Implants may be used to replace one or

more missing teeth. Immediate loading is indicated when there is good primary stability and an appropriate occlusal load.

Zimmer One-Piece 3.7 mm implants are limited to restorations (immediately loaded or loaded after a conventional healing period) in the premolar, cuspid, and incisor regions of partially edentulous jaws.

DEVICE DESCRIPTION

The purpose of this submission is to add an immediate loading single tooth indication to the following implants systems previously cleared by FDA: *Tapered Screw-Vent*, *Screw-Vent* (K013227), *AdVent* (K011245) and *Zimmer* One-Piece 3.7 mm (K052997). These implants are titanium alloy, self-tapping implants that incorporate either the MTX or MP-1 surface. There is no significant difference in design or materials between the implants in this submission and the previously cleared implants from Zimmer Dental.

EQUIVALENCE TO MARKETED DEVICE

Zimmer Dental has submitted information to demonstrate that, for the purposes of FDA's regulation of medical devices, Zimmer Dental Implants – Immediate Loading Indication are substantially equivalent in indications and design principles to predicate devices previously cleared for marketing by FDA: Zimmer Dental *Tapered Screw-Vent Implants* and *Screw-Vent Implants* (K013227, K950577), Zimmer Dental *AdVent* Implants (K011245, K002614), *Zimmer* One-Piece 3.7 mm Implant (K052997); and the Nobel Biocare TiUnite Dental Implants (K050705).

Zimmer Dental Implants - Immediate Loading Indication have the following similarities to the predicate devices:

- have the same intended use (Nobel Biocare Predicate),
- use the same operating principle,
- incorporate the same basic design
- incorporate the same materials, and
- are packaged and sterilized using the same materials and processes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 8 2006

Zimmer Dental, Incorporated
C/O Mr. Floyd G. Larson
PaxMed International, LLC
11234 EL Camino Real, Suite 200
San Diego, California 92130

Re: K061410
Trade/Device Name: Zimmer Dental Implant System
Regulation Number: 872.3640
Regulation Name: Tooth Shade Resin Material
Regulatory Class: II
Product Code: DZE
Dated: August 29, 2006
Received: August 31, 2006

Dear Mr. Larson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

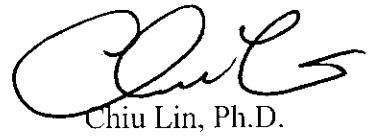
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061410

Device Name: Zimmer Dental Implant System

Indications For Use:

The *Tapered Screw-Vent*®, *Screw-Vent*®, *AdVent*®, and *Zimmer*® One-Piece 3.7 mm Dental Implants are designed for use in the maxilla or mandible for immediate loading or for loading after a conventional healing period. Implants may be used to replace one or more missing teeth. Immediate loading is indicated when there is good primary stability and an appropriate occlusal load.

Zimmer One-Piece 3.7 mm implants are limited to restorations (immediately loaded or loaded after a conventional healing period) in the premolar, cuspid, and incisor regions of partially edentulous jaws.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
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